

Remarks

Claims 24-27, 31, 32, 34-40, 42 and 47 are pending in the subject application. By this Amendment, Applicants have amended claims 24, 37, 38, and 42 and added claims 48 and 49. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed (see, for example, page 5, lines 5-15 and pages 24-33). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 24-27, 31, 32, 34-40, 42 and 47-49 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Applicants gratefully acknowledge the Examiner's apparent withdrawal of any prior rejection(s) and/or objection(s) not restated in the Office Action dated December 19, 2008.

Claims 24, 38 and 42 are objected to because of informalities. The Examiner indicates that the definite article "the" is missing in claims 24, 38 and 42. Applicants gratefully acknowledge the Examiner's careful review of the claims. The claims have been amended in accordance with the Examiner's suggestions. Reconsideration and withdrawal of the objection is respectfully requested.

Claims 24-27, 31, 32, 34-40, 42 and 47 are rejected under 35 U.S.C. § 103(a) as obvious over Rondon *et al.* (2000) in view of Chain *et al.* (2000), Groth *et al.* (2000), Berg *et al.* (1982), and if necessary in view of Devine *et al.* (U.S. Patent No. 5,728,551).

The Office Action states that the recent Supreme Court decision [KSR] "forfeits the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness." While the Supreme Court did criticize an overly rigid application of the TSM test, the Court recognized that the obviousness of a combination cannot be proved by the mere demonstration that the individual elements were known. Rather, one must be able to articulate an art-recognized rationale for making the full combination (*i.e.*, a reason for making the invention as a whole). *See KSR Intern. Co. v. Teleflex, Inc.*, 550 U.S. 398, 401 (2007).

The Office Action states that "[Rondon *et al.*] teaches screening and analyzing the clones from the generated libraries (e.g. pp.2542-2543; especially bridging para) and selection of a certain constructs such as the constructs that contain various genes (including cellulose, chitinase, keratinase, etc.) (e.g. p.2543), as well as 'selecting' DNA with certain size from the generated libraries (e.g. p.2542, left col., para 3), which read on the 'selecting step'".

Assuming for the sake of argument that such disclosures are examples of “selecting” in accordance with claim 24 step (i) and/or claim 42 step (ii), it is instructive to consider what exactly is being selected. In step (i) of claim 24, “cloning vectors in the library which contain a polynucleotide having a particular characteristic” are selected. In step (ii) of claim 42, “cloning vectors in said library which contain DNA fragments having a particular characteristic of interest” are selected. Applicants note that the constructs and libraries of Rondon *et al.* are BAC constructs and BAC libraries. Accordingly, any putative “selecting” step disclosed by Rondon *et al.* is a selection of BAC cloning vectors in a BAC library. Selection apparently may be of BAC clones that contain inserts of a particular size or that encode a function such as DNase, lipase, or amylase.

The Office Action also states that “[Rondon *et al.*] inherently teaches “integration . . . into a chromosome of a selected host cell” and that “one of the host cell ‘chromosome’ (*i.e.*, the transformed BAC) is integrated with ‘the polynucleotide’”. Rondon *et al.* teach that the polynucleotide that is integrated into the BAC is a transposon designed to inactivate a gene of interest carried on the BAC. Thus, the Office relies on integrating an inactivating transposon into a member of Rondon *et al.*’s BAC library to supply the claimed element of integrating into a chromosome.

Applicants respectfully assert that the Examiner has impermissibly combined elements without any regard to their *established* function in the prior art, in contravention of the guidance provided in *KSR Intern. Co. v. Teleflex, Inc.* Here, the Examiner has pressed the BAC vectors of Rondon *et al.* into incompatible dual service. On the one hand, the BAC vectors of Rondon *et al.* supposedly represent the ‘cloning vectors’ that are ‘selected’ in claim 24(i) and claim 42(ii). On the other hand, the BAC vectors of Rondon *et al.* are said to also represent the ‘chromosome’ into which integration occurs in claim 24(iii) and 42(iv). This would seem to be an inconsistent reading of the purported teachings of Rondon *et al.* and requires a single element found in the prior art (Rondon *et al.*) to correspond to two different elements within the claim under examination. Such an application of the teachings of Rondon *et al.* and would appear to render the BAC chromosomes unsuitable for their intended use since the BAC vectors of Rondon *et al.* must apparently be selected, modified, and then integrated into themselves. As the Patent Office is aware, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no

suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Moreover, Applicants respectfully assert that a person of ordinary skill in the art would not have been motivated to modify a vector containing a polynucleotide of interest in the manner required by the claims. Modifying a selected vector by using a transposon – when the aim is to maintain the gene of interest and *not* to inactivate it – could lead to technical difficulties and adversely effect the gene of interest, once again rendering the vector unsuitable for its intended purpose. One of skill in the art would thus be expected to use a different ordering, such as the following:

- (a) constructing a cloning vector with all elements required for integration, transfer, etc.;
- (b) inserting the gene of interest into the cloning vector (or constructing a DNA library); and
- (c) transferring this cloning vector comprising the polynucleotide of interest into the host.

In light of the above considerations, Applicants respectfully assert that the claimed invention is not obvious over the cited references. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

Claims 24-27, 31, 32, 34-40, 42 and 47 are rejected under 35 U.S.C. § 102(b) as being anticipated by Haldimann *et al.* (2001) in view of Chain *et al.* (2000), Groth *et al.* (2000), Berg *et al.* (1982), and if necessary in view of Devine *et al.* (U.S. Patent No. 5,728,551).

Applicants note that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Moreover, where a method claim requires that steps be completed in a certain order, a reference that teaches a different order, or a reference that fails to teach any particular order at all, does not anticipate the claim. *Watson & Chalin Manufacturing, Inc. v. Hendrickson USA, LLC*, Appeal 2007-2782, Inter Partes Reexam 95/000,030 (BPAI 2008) (rejecting the Examiner’s reasoning that the author of the reference “must have tried all three of the [possible] sequential variations in order to decide which possibility was preferred”).

Applicants respectfully assert that Haldimann *et al.* does not describe a method wherein every element required by the claims is expressly or inherently present. For example, Haldimann *et al.* does

not teach the use of a “target polynucleotide construct [that] comprises a nucleic acid encoding a functional origin of transfer and a nucleic acid encoding an integrase functional in a selected recipient host cell.” Although the Examiner states that Chain *et al.* teach inserting an oriT, neither this reference, nor any of the other cited references (Groth *et al.* (2000), Berg *et al.* (1982), and/or Devine *et al.* (U.S. Patent No. 5,728,551)) provide any evidence that an oriT or integrase is present in the constructs of Haldimann *et al.* Because Haldimann *et al.* does not expressly or inherently describe each and every element set forth in any claim, Haldimann *et al.* cannot anticipate any claim. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

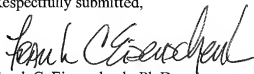
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants’ agreement with or acquiescence in the Examiner’s position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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